## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

BOSTON SCIENTIFIC CORPORATION; BOSTON SCIENTIFIC SCIMED, INC.; BOSTON SCIENTIFIC LIMITED; AND ENDOVASCULAR TECHNOLOGIES, INC.

Plaintiffs,

v.

COOK, INC.; WILSON-COOK MEDICAL, INC.; COOK MEDICAL INC.; COOK IRELAND LTD.; COOK GROUP, INC.; TAEWOONG MEDICAL CO., LTD.; STANDARD SCI-TECH INC.; ENDOCHOICE, INC.; AND SEWOON MEDICAL CO., LTD.

Defendants.

Civil Action No. 10-11646-DPW

**JURY TRIAL DEMANDED** 

# <u>DEFENDANT TAEWOONG MEDICAL CO., LTD.'S ANSWER, AFFIRMATIVE</u> <u>DEFENSES AND COUNTERCLAIMS TO FIRST AMENDED COMPLAINT</u>

Defendant TaeWoong Medical Co., Ltd ("TaeWoong"), by way of its Answer,
Affirmative Defenses and Counterclaims to the First Amended Complaint ("FAC") filed
by Boston Scientific Corporation ("BSC"), Boston Scientific Scimed, Inc. ("BSS"),
Boston Scientific Limited ("BSL"), and Endovascular Technologies, Inc. ("EVT")
(collectively, "Plaintiffs"), states as follows:

### **NATURE OF ACTION**

1. TaeWoong admits that the FAC purports to state a cause of action for patent infringement. TaeWoong denies that the FAC states such a cause of action and denies that TaeWoong committed any acts of patent infringement or that TaeWoong will do so.

### **PARTIES**

- 2. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 2 of the FAC and therefore denies the same.
- 3. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 3 of the FAC and therefore denies the same.
- 4. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 4 of the FAC and therefore denies the same.
- 5. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 5 of the FAC and therefore denies the same.

#### **Cook Defendants**

- 6. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 6 of the FAC and therefore denies the same.
- 7. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 7 of the FAC and therefore denies the same.
- 8. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 8 of the FAC and therefore denies the same.
- 9. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 9 of the FAC and therefore denies the same.
- 10. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 10 of the FAC and therefore denies the same.

11. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 11 of the FAC and therefore denies the same.

# **TaeWoong Defendant**

- 12. TaeWoong admits that it is a corporation organized under the laws of the Republic of Korea. TaeWoong denies that its principal place of business is located at Ilsan Techno-Town, 114-1, Backsuk-Dong, Ilsan-Ku, Goyang-Si, Kyunggi-Do, South Korea 411-360, but admits that it maintains an office at Ilsan Techno-Town #610, 1141-1, Baeksuk-Dong, Ilsan-Ku, Goyang-Si, Gyonggi-Do, Republic of Korea.
- 13. TaeWoong admits that it is involved in selling in the United States, offering for sale in the United States and importing into the United States, certain endoscopy products, including stents and related delivery systems such as NITI-S<sup>TM</sup> stents and delivery devices. TaeWoong denies the remaining allegations in paragraph 13 of the FAC.

#### **Standard Sci-Tech Defendants**

- 14. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 14 of the FAC and therefore denies the same.
- 15. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 15 of the FAC and therefore denies the same.

- 16. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 16 of the FAC and therefore denies the same.
- 17. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 17 of the FAC and therefore denies the same.

### **JURISDICTION AND VENUE**

- 18. TaeWoong admits that the FAC purports to state a cause of action under the United States patent laws. That this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) states a legal conclusion to which no answer is required.
- 19. The allegations in paragraph 19 of the FAC state a legal conclusion to which no answer is required. To the extent any answer is required, TaeWoong answers the following. TaeWoong denies that it has conducted or does conduct business within the Commonwealth of Massachusetts. TaeWoong admits that it is involved in selling in the United States, offering for sale in the United States and importing into the United States, certain endoscopy products for the treatment of diseases of the digestive system, including stents and delivery systems, but denies that any of these activities occurred in the Commonwealth of Massachusetts, or were directed at the Commonwealth of Massachusetts or its residents. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 19 of the FAC to the extent they are directed at the other defendants and therefore denies the same. To the extent not

already addressed, TaeWoong denies the remainder of the allegations in paragraph 19 of the FAC.

20. The allegations in paragraph 20 of the FAC state a legal conclusion to which no answer is required.

### COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,007,574

- 21. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 20 as if fully set forth herein.
- 22. TaeWoong admits that U.S. Patent No. 6,007,574 ("the '574 Patent") states on its face that it is entitled "Stent," and that it was issued by the United States Patent and Trademark Office ("USPTO") on December 28, 1999. TaeWoong also admits that the face of the '574 Patent purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. TaeWoong denies that the '574 Patent was duly and legally issued.
- 23. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 23 of the FAC and therefore denies the same.
  - 24. TaeWoong denies the allegations in paragraph 24 of the FAC.
- 25. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 25 of the FAC and therefore denies the same.
- 26. TaeWoong denies the allegations in paragraph 26 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 26 of the FAC

to the extent they are directed at the other Defendants in this case and therefore denies the same.

27. TaeWoong denies the allegations in paragraph 27 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 27 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

### COUNT II: INFRINGEMENT OF U.S. PATENT NO. 6,309,415

- 28. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 27 as if fully set forth herein.
- 29. TaeWoong admits that U.S. Patent No. 6,309,415 ("the '415 Patent") states on its face that it is entitled "Stent," and that it was issued by the USPTO on October 30, 2001. TaeWoong also admits that the face of the '415 Patent purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. TaeWoong denies that the '415 Patent was duly and legally issued.
- 30. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 30 of the FAC and therefore denies the same.
  - 31. TaeWoong denies the allegations in paragraph 31 of the FAC.
- 32. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 32 of the FAC and therefore denies the same.

- 33. TaeWoong denies the allegations in paragraph 33 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 33 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.
- 34. TaeWoong denies the allegations in paragraph 34 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 34 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

### **COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,160,323**

- 35. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 34 as if fully set forth herein.
- 36. TaeWoong admits that U.S. Patent No. 7,160,323 ("the '323 Patent") states on its face that it is entitled "Method for Reconstructing Body Lumens," and that it was issued by the USPTO on January 9, 2007. TaeWoong also admits that the face of the '323 Patent purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. TaeWoong denies that the '323 Patent was duly and legally issued.
- 37. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 37 of the FAC and therefore denies the same.
  - 38. TaeWoong denies the allegations in paragraph 38 of the FAC.

- 39. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 39 of the FAC and therefore denies the same.
- 40. TaeWoong denies the allegations in paragraph 40 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 40 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.
- 41. TaeWoong denies the allegations in paragraph 41 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 41 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

### COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 7,419,502

- 42. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 41 as if fully set forth herein.
- 43. TaeWoong admits that U.S. Patent No. 7,419,502 ("the '502 Patent") states on its face that it is entitled "Stent," and that it was issued by the USPTO on September 2, 2008. TaeWoong also admits that the face of the '502 Patent purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. TaeWoong denies that the '502 Patent was duly and legally issued.

- 44. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 44 of the FAC and therefore denies the same.
  - 45. TaeWoong denies the allegations in paragraph 45 of the FAC.
- 46. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 46 of the FAC and therefore denies the same.
- 47. TaeWoong denies the allegations in paragraph 47 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 47 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.
- 48. TaeWoong denies the allegations in paragraph 48 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 48 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

#### COUNT V: INFRINGEMENT OF U.S. PATENT NO. 7,419,503

- 49. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 48 as if fully set forth herein.
- 50. TaeWoong admits that U.S. Patent No. 7,419,503 ("the '503 Patent") states on its face that it is entitled "Stent," and that it was issued by the USPTO on September 2, 2008. TaeWoong also admits that the face of the '503 Patent purports to

- name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. TaeWoong denies that the '503 Patent was duly and legally issued.
- 51. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 51 of the FAC and therefore denies the same.
  - 52. TaeWoong denies the allegations in paragraph 52 of the FAC.
- 53. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 53 of the FAC and therefore denies the same.
- 54. TaeWoong denies the allegations in paragraph 54 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 54 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.
- 55. TaeWoong denies the allegations in paragraph 55 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 55 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

#### COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 7,736,386

56. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 55 as if fully set forth herein.

- 57. TaeWoong admits that U.S. Patent No. 7,736,386 ("the '386 Patent") states on its face that it is entitled "Stent," and that it was issued by the USPTO on June 15, 2010. TaeWoong also admits that the face of the '386 Patent purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. TaeWoong denies that the '386 Patent was duly and legally issued.
- 58. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 58 of the FAC and therefore denies the same.
  - 59. TaeWoong denies the allegations in paragraph 59 of the FAC.
- 60. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 60 of the FAC and therefore denies the same.
- 61. TaeWoong denies the allegations in paragraph 61 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 61 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.
- 62. TaeWoong denies the allegations in paragraph 62 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 62 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

### COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 7,763,068

- 63. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 62 as if fully set forth herein.
- 64. TaeWoong admits that U.S. Patent No. 7,763,068 ("the '068 Patent") states on its face that it is entitled "Stent," and that it was issued by the USPTO on July 27, 2010. TaeWoong also admits that the face of the '068 Patent purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. TaeWoong denies that the '068 Patent was duly and legally issued.
- 65. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 65 of the FAC and therefore denies the same.
  - 66. TaeWoong denies the allegations in paragraph 66 of the FAC.
- 67. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 67 of the FAC and therefore denies the same.
- 68. TaeWoong denies the allegations in paragraph 68 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 68 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.
- 69. TaeWoong denies the allegations in paragraph 69 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 69 of the FAC

to the extent they are directed at the other Defendants in this case and therefore denies the same.

### **COUNT VIII: INFRINGEMENT OF U.S. PATENT NO. 6,533,810**

- 70. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 69 as if fully set forth herein.
- 71. TaeWoong admits that U.S. Patent No. 6,533,810 ("the '810 Patent") states on its face that it is entitled "Conical Stent," and that it was issued by the USPTO on March 18, 2003. TaeWoong also admits that the face of the '810 Patent purports to name S. Hankh, M. Gianotti, and E. Hofmann as the inventors. TaeWoong denies that the '810 Patent was duly and legally issued.
- 72. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 72 of the FAC and therefore denies the same.
  - 73. TaeWoong denies the allegations in paragraph 73 of the FAC.
- 74. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 74 of the FAC and therefore denies the same.
- 75. TaeWoong denies the allegations in paragraph 75 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 75 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

76. TaeWoong denies the allegations in paragraph 76 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 76 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

### COUNT IX: INFRINGEMENT OF U.S. PATENT NO. 6,818,015

- 77. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 76 as if fully set forth herein.
- 78. TaeWoong admits that U.S. Patent No. 6,818,015 ("the '015 Patent") states on its face that it is entitled "Conical Stent," and that it was issued by the USPTO on November 16, 2004. TaeWoong also admits that the face of the '015 Patent purports to name S. Hankh, M. Gianotti, and E. Hofmann as the inventors. TaeWoong denies that the '015 Patent was duly and legally issued.
- 79. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 79 of the FAC and therefore denies the same.
  - 80. TaeWoong denies the allegations in paragraph 80 of the FAC.
- 81. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 81 of the FAC and therefore denies the same.
- 82. TaeWoong denies the allegations in paragraph 82 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 82 of the FAC

to the extent they are directed at the other Defendants in this case and therefore denies the same.

83. TaeWoong denies the allegations in paragraph 83 of the FAC to the extent they are directed at TaeWoong. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 83 of the FAC to the extent they are directed at the other Defendants in this case and therefore denies the same.

### COUNT X: INFRINGEMENT OF U.S. PATENT NO. 5,876,448

- 84. TaeWoong repeats its answers to the allegations contained in paragraphs 1 through 83 as if fully set forth herein.
- 85. TaeWoong admits that U.S. Patent No. 5,876,448 ("the '448 Patent") states on its face that it is entitled "Esophageal Stent," and that it was issued by the USPTO on March 2, 1999. TaeWoong also admits that the face of the '448 Patent purports to name R.J. Thompson, J.E. Laptewicz, Jr., and P.J. Thompson as the inventors. TaeWoong denies that the '448 Patent was duly and legally issued.
- 86. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 86 of the FAC and therefore denies the same.
- 87. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 87 of the FAC and therefore denies the same.

88. TaeWoong is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 88 of the FAC and therefore denies the same.

### PRAYER FOR RELIEF

TaeWoong denies that Plaintiffs are entitled to any relief, specifically denies each allegation and request for relief in paragraphs (a) through (e) of Plaintiffs' Prayer for Relief, and prays for judgment in favor of TaeWoong dismissing this action and awarding TaeWoong its reasonable attorneys' fee pursuant to 35 U.S.C. § 285, interest, and costs in this action, and any further relief that this Court deems just and proper.

### **AFFIRMATIVE DEFENSES**

# FIRST AFFIRMATIVE DEFENSE FAILURE TO STATE A CLAIM

89. The First Amended Complaint fails to state a claim upon which relief can be granted.

# SECOND AFFIRMATIVE DEFENSE $\underline{LACHES}$

90. Plaintiffs' claims are barred by the equitable doctrine of laches.

# THIRD AFFIRMATIVE DEFENSE LIMITATION OF DAMAGES

91. Any claim for damages by Plaintiffs is limited by 35 U.S.C. § 287 to only those damages occurring after proper notice of infringement to TaeWoong.

## FOURTH AFFIRMATIVE DEFENSE NONINFRINGEMENT

92. TaeWoong is not infringing, has not infringed, nor will it infringe, either literally or under the doctrine of equivalents any claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent or '015 Patent, nor has it induced or contributed to the infringement of any claims of those patents.

# FIFTH AFFIRMATIVE DEFENSE INVALIDITY

93. All of the claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent and '015 Patent are invalid for failure to comply with the requirements of 35 U.S.C. §§ 101, *et seq.*, including 35 U.S.C. §§ 101, 102, 103 and/or 112.

# SIXTH AFFIRMATIVE DEFENSE <u>UNENFORCEABILITY</u>

94. All of the claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent and '068 Patent are unenforceable due to inequitable conduct and/or unclean hands, including the acts and failures to act set forth more fully in paragraphs 23 through 55 of TaeWoong's Counterclaims alleged below, which are incorporated herein by reference.

# SEVENTH AFFIRMATIVE DEFENSE <u>ESTOPPEL</u>

95. Based on amendments, admissions, representations and/or statements made during prosecution of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503

Patent, '386 Patent, '068 Patent, '810 Patent and '015 Patent before the USPTO,

Plaintiffs are now estopped and otherwise precluded from maintaining that such claims

are of sufficient scope to cover the accused products, either literally or under the doctrine
of equivalents.

# EIGHTH AFFIRMATIVE DEFENSE NO EXCEPTIONAL CASE

96. Plaintiffs have pled no valid basis for finding an exceptional case.

### **RESERVATION OF DEFENSES**

97. To the extent not already pled, TaeWoong reserves the right to add additional defenses pending further investigation and discovery in this case.

### **COUNTERCLAIMS OF TAEWOONG MEDICAL CO., LTD.**

- 1. This is an action for a declaration of non-infringement, invalidity and unenforceability of various United States Patents pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and for such other and further relief as the Court deems just and proper.
- 2. TaeWoong brings this action for at least the following declarations: (i) each of the claims of United States Patent Nos. 6,007,574 ("'574 Patent"), 6,309,415 ("'415 Patent"), 7,160,323 ("'323 Patent"), 7,419,502 ("'502 Patent"), 7,419,503 ("'503 Patent"), 7,736,386 ("'386 Patent"), 7,763,068 ("'068 Patent"), 6,533,810 ("'810 Patent"), and 6,818,015 ("'015 Patent") are invalid; (ii) each of the claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, and '068 Patent are unenforceable; and (iii) TaeWoong has not before, and does not now, infringe any

claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent, and '015 Patent.

### **PARTIES**

- 3. Defendant/Counterclaim-Plaintiff TaeWoong Medical Co., Ltd.

  ("TaeWoong") is a corporation organized under the laws of the Republic of Korea, with a principal place of business located at 1-5, Gomak-ri, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Republic of Korea.
- 4. Plaintiff/Counterclaim-Defendant Boston Scientific Corp. ("BSC") alleges that it is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 1 Boston Scientific Pl., Natick, MA 01760 and that it is the owner by assignment of the '810 and '015 Patents.
- 5. Plaintiff/Counterclaim-Defendant Boston Scientific Limited ("BSL") alleges that it is a corporation organized and existing under the laws of Ireland with a principal place of business at Ballybrit Business Park, Galway, Ireland and that it is a wholly owned subsidiary of BSC. BSC alleges that it is an exclusive licensee of the '574, '415, '323, '502, '503, '386, and '068 Patents.
- 6. Plaintiff/Counterclaim-Defendant Endovascular Technologies ("EVT") alleges that it is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 4100 Hamline Avenue North, St. Paul, MN 55112 and that it is a wholly owned subsidiary of BSC. EVT alleges that it is the owner by assignment of the '574, '415, '323, '502, '503, '386, and '068 Patents.

### **JURISDICTION AND VENUE**

- 7. This Court has subject matter jurisdiction over these counterclaims under the laws of the United States, 28 U.S.C. § 1331 (federal question); § 1338(a) (as civil action arising under any act of Congress relating to patents); and §§ 2201 and 2202 (as a declaratory action in a case of actual controversy within the jurisdiction of a federal court).
- 8. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants BSC, BSL and EVT because each has submitted to the jurisdiction of this Court by filing a complaint for patent infringement in this Court in the above-captioned action.
- 9. To the extent that venue for the underlying complaint is proper, venue for the underlying action is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and/or 1400(b).

### THE PATENTS IN SUIT

- 10. The '574 Patent, which on its face states that it is entitled "Stent", was purportedly issued by the United States and Patent Office ("USPTO") on December 28, 1999, to S.A. Pulnev, A.V. Karev, and S.V. Schukin as the purported inventors.
- 11. The '415 Patent, which on its face states that it is entitled "Stent," was purportedly issued by the USPTO on October 30, 2001 to S.A. Pulnev, A.V. Karev, and S.V. Schukin as the purported inventors.
- 12. The '323 Patent, which on its face states that it is entitled "Method for Reconstructing Body Lumens," was purportedly issued by the USPTO on January 9, 2007, to S.A. Pulnev, A.V. Karev, and S.V. Schukin as the purported inventors.

- 13. The '502 Patent, which on its face states that it is entitled "Stent," was purportedly issued by the USPTO on September 2, 2008, to S.A. Pulnev, A.V. Karev, and S.V. Schukin as the purported inventors.
- 14. The '503 Patent, which on its face states that it is entitled "Stent," was purportedly issued by the USPTO on September 2, 2008, to S.A. Pulnev, A.V. Karev, and S.V. Schukin as the purported inventors.
- 15. The '386 Patent, which on its face states that it is entitled "Stent," was purportedly issued by the USPTO on June 15, 2010, to S.A. Pulnev, A.V. Karev, and S.V. Schukin as the purported inventors.
- 16. The '068 Patent", which on its face states that it is entitled "Stent," was purportedly issued by the USPTO on July 27, 2010, to S.A. Pulnev, A.V. Karev, and S.V. Schukin as the purported inventors.
- 17. The '810 Patent, which on its face states that it is entitled "Conical Stent," was purportedly issued by the USPTO on March 18, 2003, to S. Hankh, M. Gianotti, and E. Hofmann as the purported inventors.
- 18. The '015 Patent, which on its face states that it is entitled "Conical Stent," was purportedly issued by the USPTO on November 16, 2004, to S. Hankh, M. Gianotti, and E. Hofmann as the purported inventors.

## **BACKGROUND**

19. On September 27, 2010, Plaintiffs/Counterclaim-Defendants BSC, BSL and EVT filed a Complaint in the above-captioned action for alleged patent infringement against Defendant/Counterclaim-Plaintiff TaeWoong in the United States District Court for the District of Massachusetts.

- Plaintiffs/Counterclaim-Defendants then filed a First Amended Complaint
   ("FAC") against TaeWoong on December 2, 2010.
- 21. The FAC alleges that TaeWoong infringed, induced infringement and/or contributed to the infringement of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent, and '015 Patent by allegedly making, using, selling, offering to sell and/or importing in the United States endoscopy products for the treatment of diseases of the digestive system, including, but not limited to, stents and related delivery systems such as the NITI-S<sup>TM</sup> stents and delivery devices.
- 22. By filing the FAC, Plaintiffs/Counterclaim-Defendants have created an actual controversy with TaeWoong concerning whether the claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent and '015 Patent are infringed, valid and/or enforceable.
- 23. On information and belief, the named inventors of the '574 Patent and/or their agents, attorneys, and assigns (collectively, "Applicants") committed inequitable conduct during prosecution that renders unenforceable the '574 Patent and any associated patent claiming priority thereto, including the related '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent and '068 Patent, each of which share common disclosure on which the claims of the '574 Patent are based.
- 24. On information and belief, the '574 Patent issued from U.S. Application No. 08/860,462 ("the '462 application").
- 25. On information and belief, the '462 application claimed priority to Patent Cooperation Treaty ("PCT") application No. PCT/RU94/00292 (the "PCT application"), which was filed on December 23, 1994.

- 26. On information and belief, the PCT application claimed priority to Russian Patent application No. 93058166 (the "Russian application"), which was filed on December 28, 1993.
- 27. On information and belief, the named inventors on the '574 Patent were also named as inventors in each of the Russian and the PCT applications.
- 28. On information and belief, the Russian and PCT applications were filed solely in the name of the three named inventors.
- 29. Under United States patent prosecution procedure at the time of the prosecution of the '462 application, there was a statutory 30-month deadline under 35 U.S.C. §371(b) for entering the national stage under the PCT by filing an application in the USPTO claiming the benefit of an earlier filing of a corresponding PCT application.
- 30. This 30-month deadline was measured from an application's earliest claimed priority date, which in the case of the '462 application was the Russian application filing date of December 28, 1993. Therefore, the 30-month deadline for entering the national stage under the PCT was June 28, 1996.
- 31. On information and belief, the steps necessary to enter the national stage under the PCT by filing an application in the USPTO claiming the benefit of an earlier filing of a corresponding PCT application were not taken by the Applicants by the June 28, 1996 deadline.
- 32. On information and belief, the Applicants instead, through their attorney J. Bennett Mullinax, submitted application papers including, *inter alia*, a purported English translation of the PCT application and a paper entitled "Petition for Revival of the Application under 37 C.F.R. §1.137(b)" ("the Petition").

- 33. The Petition was executed on June 16, 1997 and then was not mailed until some eleven (11) days later on June 27, 1997, almost one year after the statutory 30-month deadline for claiming priority from the PCT application, and a mere day before the one-year deadline for filing the Petition.
- 34. On information and belief, the Applicants in the Petition requested that the USPTO revive the '462 application despite the Applicants' failure by the June 28, 1996 deadline to take the necessary steps to enter the national stage under the PCT by filing an application in the USPTO claiming the benefit of an earlier filing of a corresponding PCT application.
- 35. On information and belief, Mr. Mullinax represented to the USPTO in the Petition that: "The delay to prosecute said application was unintentional. Abandonment occurred for failure to timely enter the U.S. National Phase of PCT prosecution by 28 June 1996. This Petition is filed within one year of the date on which the application became abandoned."
- 36. On information and belief, P.F. Kratz, the USPTO's petition reviewing officer, on November 24, 1997, dismissed the Petition without prejudice based on problems with the English translation document submitted with the application papers that were filed on June 27, 1997.
- 37. On information and belief, Mr. Mullinax then filed a response on January 22, 1998, entitled "Renewed Petition Under 37 C.F.R. § 1.137(b)", which included a purportedly proper English translation of the PCT application.

- 38. On information and belief, the USPTO petition-reviewing officer then granted the Applicants' Petition to revive the application on May 11, 1998. The USPTO thereafter recognized Applicants' claim for priority to the PCT and Russian applications.
- 39. On information and belief, Mr. Mullinax's June 1997 statement, that the failure to take the necessary steps by the June 28, 1996 deadline was "unintentional," was a knowingly false statement made to mislead the USPTO and the USPTO petition-reviewing officer.
- 40. On information and belief, Mr. Mullinax's June 1997 statement suggests an attempt to satisfy (without proper basis) PTO petition practice, and not the true and accurate circumstances of the delay in the bringing of the petition.
- 41. On information and belief, the Applicants' failure to take the necessary steps to enter the national stage under the PCT by filing an application in the USPTO claiming the benefit of an earlier filing of a corresponding PCT application before the statutory 30-month deadline could not have been unintentional for several reasons.
- 42. First, the Declaration submitted with the application papers on June 27, 1997 was purportedly executed by each named inventor well before the expiration of the June 28, 1996 deadline. Named inventor S.A. Pulnev purportedly executed the submitted Declaration on June 14, 1996; named inventor A.V. Karev purportedly executed the submitted Declaration on June 14, 1996; and named inventor S.V. Schukin purportedly executed the submitted Declaration on June 6, 1996.
- 43. Second, the Declaration was specifically prepared to be submitted with the filing of a U.S. national phase PCT application claiming priority to the PCT application.

- 44. The most reasonable conclusions to be drawn from the preparation of the Declaration and the dates on which the named inventors executed that Declaration are that the Applicants were acting knowingly and deliberately with respect to securing United States patent rights and that they were aware of the deadline by which they had to do so.
- 45. Therefore, Mr. Mullinax's statement in the Petition of June 1997 that the delay in prosecuting the U.S. national phase PCT application was "unintentional" is inaccurate in light of these facts.
- 46. Third, on information and belief, the Applicants filed a European national phase application (EP Application No. 95905819.9 "the EPO application") with the European Patent Office ("EPO"), through their European counsel, D.H. Stringer of W.P. Thompson & Co., on July 24, 1996.
- 47. On information and belief, the EPO application was filed within the EPO's requirement of filing an EPO national stage PCT application no later than 31 months from the earliest priority date, *i.e.*, by July 28, 1996.
- 48. Upon information and belief, just as in the United States, the EPO application claimed priority to the PCT application, which ultimately claimed priority to the Russian application.
- 49. By filing the EPO application, the Applicants and their various patent counsel demonstrated that they were aware of the world-wide PCT nationalization régimes and the required filing deadlines in the United States and Europe, and were actively and deliberately seeking to file in the United States and Europe in June and July, 1996.

- 50. Therefore, Mr. Mullinax's statement of alleged "unintentional" delay in submitting the Petition can only have been made with the intent to deceive the USPTO and the petition review officer in order to obtain a granted Petition and thereby revive the application that had become abandoned for failure to meet the statutory 30-month deadline.
- 51. In view of the circumstances, the false and misleading statement regarding "unintentional" delay in the Petition and reaffirmation thereof by way of the Renewed Petition is highly material to patentability because of the Applicants' claim for priority to the PCT and Russian applications.
- 52. Because the PCT application published on July 6, 1995, the PCT application would have been anticipatory prior art to the '462 application under 35 U.S.C. § 102(b) (having published more than one year prior to the granted filing date of the '462 application) had the '462 application not been given the benefit of a priority claim to the PCT application.
- 53. Without the priority claim, at least claim 1 of the '574 Patent, among other claims in the aforementioned related patents, would not have been allowed to issue because the disclosure in the published PCT application is the purported basis for the claimed subject matter.
- 54. Based on these facts, Mr. Mullinax's statement in the Petition about "unintentional" delay in prosecuting the application that became the '462 application was false, made with specific intent to mislead and deceive the USPTO and highly material to patentability.

55. Because of this inequitable conduct committed during prosecution of the '462 application, the '574 Patent that issued from the '462 application and its associated related patents, including the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, and the '068 Patent, all of which share a common priority claim rendered illegitimate in view of Mr. Mullinax's false statement, should be deemed unenforceable.

# COUNT I DECLARATION OF NONINFRINGEMENT OF PATENTS

- 56. TaeWoong realleges and incorporates by reference the allegations contained in paragraphs 1 through 55 of its Counterclaims as if set forth fully herein.
- 57. TaeWoong seeks a judicial declaration that it does not directly or indirectly infringe any claim of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent or '015 Patent through any activities related to its use, manufacture, sales, offers to sell and/or importation in the United States of endoscopy products for the treatment of diseases of the digestive system, including, but not limited to, stents and related delivery systems such as the NITI-S<sup>TM</sup> stents and delivery devices, which declaration is appropriate and necessary.

# COUNT II <u>DECLARATION OF INVALIDITY OF PATENTS</u>

- 58. TaeWoong realleges and incorporates by reference the allegations contained in paragraphs 1 through 57 of its Counterclaims as if set forth fully herein.
- 59. Upon information and belief, each claim of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent and '015

Patent is invalid for, among other things, failing to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 101, 102, 103 and/or 112.

60. Judicial declaration of the invalidity of the claims of the said patents is appropriate and necessary.

# COUNT III <u>DECLARATION OF UNENFORCEABILITY OF PATENTS</u>

- 61. TaeWoong realleges and incorporates by reference the allegations contained in paragraphs 1 through 60 of its Counterclaims as if set forth fully herein.
- 62. Based on information presently available, and without prejudice to amendment upon information found during discovery, all of the claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent and '068 Patent are unenforceable because individuals owing a duty of candor to the USPTO, including applicants for the said patents, the attorneys prosecuting that patent, and others associated with Plaintiffs and/or their predecessors in title (collectively, the "Applicants"), engaged in inequitable conduct through disclosures made and not made to the USPTO during prosecution as described more fully in paragraphs 23 through 55 of TaeWoong's Counterclaims.
- 63. Judicial declaration of the unenforceability of the claims of the said patents is appropriate and necessary.

### PRAYER FOR RELIEF

WHEREFORE, TaeWoong respectfully requests that the Court enter judgment, as follows:

- A. That each of the claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent, and '015 Patent are invalid;
- B. That each of the claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, and '068 Patent are unenforceable;
- C. That TaeWoong does not infringe directly or indirectly any claims of the '574 Patent, '415 Patent, '323 Patent, '502 Patent, '503 Patent, '386 Patent, '068 Patent, '810 Patent, or '015 Patent;
- D. That this case is exceptional such that, pursuant to 35 U.S.C. § 285, TaeWoong be awarded its attorneys' fees and costs; and
- E. TaeWoong be granted such other and further relief as the Court may deem just and proper.

### JURY DEMAND

TaeWoong hereby demands trial by jury of all issues so triable by a jury in this action, including claims and counterclaims.

Dated: January 31, 2011 Respectfully submitted,

/s/ C. Bruce Hamburg

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### **CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on the above date.

/s/ C. Bruce Hamburg

C. Bruce Hamburg